HHS SBIR RFA-HL-14-026

NOTE: The Solicitations and topics listed on this site are copies from the various SBIR agency solicitations and are not necessarily the latest and most up-to-date. For this reason, you should use the agency link listed below which will take you directly to the appropriate agency server where you can read the official version of this solicitation and download the appropriate forms and rules.

The official link for this solicitation is: http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-026.html

Agency:
Department of Health and Human Services

Release Date:
November 18, 2013
Branch:
n/a

Open Date:
November 18, 2013
Program / Phase / Year:
SBIR / Phase I / 2014

Application Due Date:
February 10, 2015

Solicitation:
RFA-HL-14-026

Close Date:
February 10, 2015
Topic Number:
RFA-HL-14-026

Description:
Purpose

The objective of this Funding Opportunity Announcement (FOA) is to support the development of microfluidic devices to evaluate blood of pediatric/neonatal patients. Devices designed to analyze thrombotic, transfusion, and/or hemostatic conditions of blood are of interest. Many clinical laboratory-based testing procedures require relatively large volumes of blood for analysis. Excessive blood draws can result in anemia and require corrective transfusions in critically ill pediatric/neonatal patients. As a result, these critical blood evaluations may not be performed, or are performed infrequently in pediatric/neonatal patients due to the risk of depleting their limited blood volumes. Microfluidic devices which analyze microliter or nanoliter quantities of blood could represent a significant means of achieving blood conservation in pediatric intensive care populations.

In this FOA, the NHLBI will support the development of microfluidic devices capable of analyzing minute quantities of blood for a variety of cellular and protein biomarkers for thrombotic, transfusion, and/or hemostatic conditions. The proposed devices should be automated, rapid, user friendly, and not require highly trained individuals to perform these tests. All microfluidic design options are acceptable (ie. digital or microchannel), with ideal designs being portable, sensitive, and having commercial potential. Multifunctional microfluidic platform designs that make the most efficient use of blood samples are encouraged. This FOA seeks applications that expand the potential of microfluidic devices to perform blood analysis in both clinical and research settings.
Background

Recent advances in microfluidic technology (ie. lab-on-a-chip) have demonstrated significant potential to perform a wide variety of analytical procedures. Assays developed for the microfluidic platform have included immunofluorescence, DNA/RNA techniques, proteomics, mass spectrometry, and cell sorting, among others. The capability of microfluidic devices to analyze small volumes of whole blood or sera makes this technology ideally suited to a variety of clinical applications, particularly those involving pediatric/neonatal subjects for whom sample size and sampling frequency must necessarily be limited. In an attempt to reduce phlebotomy-related blood loss, devices that analyze sample sizes of approximately 100 microliters or less are preferred. Also, by utilizing small volumes of samples and reagents, microfluidic devices offer the potential for reduced cost and shortened assay run times, when compared with standard laboratory-based testing. In the clinical setting, rapid turnaround times for blood analysis could have an added advantage of leading to faster diagnosis and treatment times.

Complex changes of blood system physiology occur rapidly in sick children and newborns. Within the blood system, changes in cellular and protein components play critical roles in hemostasis and wound healing. For example, adequate platelet concentrations are essential for proper hemostatic functions. Patients with abnormally low levels of platelets run serious risks of internal hemorrhage. Also, imbalances in the levels of clotting factors can quickly place patients at risk for hemorrhage, thrombosis, or stroke. Consequently, pediatric and neonatal patients require frequent monitoring of their blood for change in status of hemostatic and/or thrombotic conditions due to receiving various treatment regimens. This is particularly true for individuals following platelet or RBC transfusions. Of the 250,000 admissions to pediatric intensive care units each year, approximately half will require at least one RBC transfusion. Additionally, many also receive IV fluids which may alter the hemostasis/thrombosis equilibrium. Monitoring the effects of these treatments can be particularly challenging in patients with small body mass and low body blood volumes. With limited blood sample sizes, microfluidic devices could serve an important role in providing a more efficient way to monitor blood values in these patients.

In addition to the clinical applications, microfluidic devices could also provide an opportunity for pediatric/neonatal patients to participate in drug research and development studies. Historically there has been a lack of testing of new drug candidates in pediatric populations in the U.S., resulting in a lag of FDA-approved therapies for these patients. The current lack of body-size appropriate blood testing procedures represents one hurdle that prevents pediatric participation in numerous clinical and research studies. Testing in pediatric patients serves another critical role, since children differ from adults in both physiology and pharmacologic response to drug therapies. Microfluidic technology offers the potential of greater pediatric participation in clinical trials and subsequently improved drug safety and efficacy for these subjects. As an example, microfluidic devices could facilitate pharmacokinetic analysis of new drugs in pediatric/neonatal populations which could potentially improve the availability of these new agents for pediatric use.

Microfluidic devices could also be particularly useful in research studies of thrombosis, hemostasis, or transfusion medicine in pediatric subjects. Devices with capabilities for studying anti-thrombotic therapies or congenital and acquired bleeding disorders, would be of interest. As an example, microfluidic devices have been shown to be particularly useful for studying cellular functions such as platelet adhesion and platelet activation. Devices capable of analyzing blood clotting mechanisms, anti-clotting mechanisms, hemorrhage or anticoagulation therapy monitoring could be applied to these important areas of clinical research. Studies of optimal transfusion practices, cell sorting capabilities to measure cellular levels in blood samples, or levels of platelet activation would be of interest also.

Microfluidic Design Characteristics of Interest:

- Automated, user friendly operation
- Cost effective
- Rapid, easily interpretable results
- Capable of analyzing small volumes of blood, 100 microliters or less is preferred
- Portable

Clinical and Research Blood Tests May Include, but Are Not Limited to:

- Monitoring coagulation status, both qualitative and quantitative, of pediatric subjects enrolled in clinical trials.
- Quantitative monitoring of glucose, lactate, urea, electrolytes, blood gases, bilirubin, and hematocrit levels.
- Monitoring of total platelet counts, platelet functional assays, and RBC counts to determine the requirement for and effectiveness of platelet and RBC transfusions.
- Hemostatic profile evaluation (ie. coagulation status) of patients receiving new generation anti-coagulant medications.
- Blood chemistries.

Projects outside the Scope of this FOA:

- Projects outside the field of thrombosis, hemostasis, or transfusion medicine or research
- Designs which are not easily adaptable to a clinical setting
- Designs lacking commercial potential